510(K) Summary

Submitter:	Cynosure, Inc. 5 Carlisle Road Westford, MA 01886
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	December 31, 2007
Device Trade Name:	Cynosure Affirm Family Laser with XPL Handpiece and Er:YAG Laser Module
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.4810
Equivalent Device:	Cynosure YAG MIR II Family laser, and Cynosure PhotoSilk Plus Pulsed Light System with Laser Attachment
Device Description:	The Affirm Family Laser with XPL Handpiece and Er:YAG Laser Module is a Nd:YAG laser system. It emits wavelengths at 1064nm, 1320nm, and 1440nm. It also incorporates an XPL Handpiece an a Er:YAG Module. Laser emission activation is by foot switch. Overall weight of the laser is 180 lbs., and the size is 65" x 23" x 68" (LxWxH). Electrical requirement is 230 VAC, 15A, 50-60 Hz, single phase.
Intended Use:	1064nm: The Cynosure Affirm Family laser is intended for the coagulation and hemostasis of benign vascular lesions, such as , but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), Café au lait macules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. 1320nm: The Cynosure Affirm Family laser is indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles. It is also indicated for the treatment of fine lines and wrinkles. 1440nm: The Cynosure Affirm Family laser is indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles and pigmented lesions. The XPL Pulsed Light System Handpierce is intended for permanent hair reduction and the treatment of dermatological vascular lesions, facial and leg veins, benign pigmented lesions, and inflammatory acne. The Affirm Family System Laser Attachment is intended for: Er:YAG 2,940 nm - for skin resurfacing and for the incision, excision, ablation or vaporization of soft bodily tissues.

Comparison:	The Cynosure Affirm Family Laser with XPL Handpiece and Er:YAG Laser Module has the same indications for use, the same principle of operation, and the same wavelength as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The CynosureAffirm Family Laser is a safe and effective device for the indications specified.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Cynosure
% Mr. George Cho
Sr. Vice President
5 Carlisle Road
Westford, Massachusetts 01886

Re: K080006
Trade/Device Name: Cynosure Affirm Family Laser with Er:YAG Laser Module
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 19, 2008
Received: February 20, 2008

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Cynosure Affirm Family Laser with Er:YAG Laser Module

Indications For Use:

1064nm: The Cynosure Affirm Family laser is intended for the coagulation and hemostasis of benign vascular lesions, such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), Café au lait macules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

1320nm: The Cynosure Affirm Family laser is indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles. It is also indicated for the treatment of fine lines and wrinkles.

1440nm: The Cynosure Affirm Family laser is indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles and pigmented lesions.

The XPL Pulsed Light System Handpiece is intended for permanent hair reduction and the treatment of dermatological vascular lesions, facial and leg veins, benign pigmented lesions, and inflammatory acne.

The Affirm Family System Laser Attachment is intended for:
Er:YAG 2,940 nm - for skin resurfacing and for the incision, excision, ablation or vaporization of soft bodily tissues.

Prescriptive Use X OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080006